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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,483	03/22/2004	Hans-Juergen Kuhr	9134-0252	2791

64108 7590 10/18/2007

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
10/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,483	KUHR ET AL.	
	Examiner	Art Unit	
	Amy T. Lang	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-26 and 29-32* is/are rejected.

7)☒ Claim(s) *19,27-28 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed drive mechanism that propels the needle from a resting position to a lancing position must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claim 18** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Although the instant specification properly recites wherein the actuation of the blocking mechanism breaks the needle body (see paragraph [0030]), it is the examiner's position that the instant specification does not explain as to how the needle body is broken, where it is broken, and what breaks it.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1-13, 15-18, 20-23, 25, 26, and 29-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 5,797,942) in view of Looper (US 2003/0114839 A1).

With regard to **claims 1, 11, 12, 15, 16, 17, 18, 21, 23, 25, 29, and 30**, Schraga discloses a re-useable lancing aid (100) for producing an opening in the skin (see entire document). The lancing aid comprises a removable lancet system (60) having a body and a needle with a needle tip (61) (Figure 2; column 5, lines 15-20). The needle body further comprises removable cap (62) that can be moved relative to the body and therefore overlaps the instantly claimed protective portion (column 5, lines 20-25). In a first packaged position the needle body surrounds the needle tip and is released for use so that the cap does not surround the needle tip in a second position (Figure 2; column 5, lines 27-30).

The lancet system (60) is inserted onto the lancet receiving assembly (120) of the lancing aid and enclosed by re-useable end cap (10) to activate the device (column 5, lines 23-30). Lancet system (60) comprises ridges (65) that interact with the lancet receiving assembly (120) and therefore overlap the instantly claimed holding elements (Figure 2). As shown in Figure 5A, the re-useable end cap (10) of the lancing aid comprises opening (19) that the needle can emerge from during a lancing operation. Trigger (130) causes the lancet to fire into a patient to draw a sample of blood and therefore overlaps the instantly claimed drive mechanism.

Although Schraga teaches a re-useable lancing device wherein the distal lancet system is detached and then disposed after use due to contamination (column 5, lines 55-56), Schraga does not specifically disclose a blocking mechanism that prevents the contaminated lancet from re-use. However, Schraga is open to various modifications and changes (column 9, lines 54-60).

Looper discloses a surgical device wherein a distal end effector is prevented from re-use (see entire document). The end effector includes a biopsy collector, which encompasses lancet devices, and is connected to the shaft of the surgical device through a frangible portion ([0014]; [0017]; [0040]). Once the distal end effector has been utilized and is contaminated, the frangible connection is distorted so that the connection between the surgical device and the end effector is prevented (Figures 2 and 3). This assures that the end effector is used only once for safety ([0043]; [0047]).

Schraga discloses a lancing device with a detachable end effector, the lancet system, that once used is contaminated and must be disposed of for safety issues. It is well known in the art to one of ordinary skill that contamination from a lancet can poses a health hazard if not properly handled. Looper teaches an advantageous blocking method wherein the end effector is prevented from being used more than once so that a contaminated end effector is not re-used. Since Schraga is open to various modifications and Looper teaches an advantageous way to prevent a lancet system from being used more than once, it would have been obvious to one of ordinary skill at the time of the invention for the lancet device of Schraga to comprise the blocking

mechanism of Looper so that the lancet system of Schraga has a frangible connection with the lancing aid.

With regard to **claims 2, 4-6, 13, and 20**, the connection between the lancet system (60) and the lancet receiving assembly is therefore prevented once the lancet system has been removed from the lancing aid. Since this connection is a frangible connection on the needle body that is broken, the shape of the needle body therefore changes and becomes smaller.

With regard to **claim 3**, as shown in Figure 2, ridges (65) are independent acting holding elements that coincide with independent grooves within the lancet receiving assembly.

With regard to **claims 7-9 and 22**, although Looper teaches the blocking mechanism actuated when the end effector is removed from the surgical device, Looper does not specifically disclose the actuation when the end effector is connected to the device or during the lancing operation. However, it would have been obvious to one of ordinary skill at the time of the invention for the blocking mechanism to be actuated when connected to the device or during the lancing operation. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify when the frangible connection is broken because Applicant has not disclosed that actuating the actuation before, during, or after the lancing operation provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected

Applicant's invention to perform equally well with the actuation when the lancet is removed because the connection is still broken to prevent re-use.

With regard to **claim 10**, Schraga discloses that after the lancet operation, the needle tip is enclosed with a protective cap to facilitate proper disposal of the contaminated lancet (column 9, lines 26-35). Although Schraga does not specifically disclose the protective cap as removable cap (62), since the removable cap also encloses the needle tip it would have been obvious to one of ordinary skill at the time of the invention for the removable cap (62) to be replaced on the lancet after the lancing operation to conceal the contaminated tip while disposing of the lancet.

With regard to **claim 26**, as shown in Figure 2 of Schraga, lancet (60) comprises a ring that is moveable with respect to the lancet receiving assembly (120). When the blocking mechanism is activated by breaking a frangible connection in lancet (60), the movable ring is prevented from interacting with member (120).

With regard to **claims 31 and 32**, since the lancet system of Schraga is able to move between a resting position and a lancing position until engagement means (30) is activated by the user (Figures 5A and 5B), the needle is therefore configured to move between these two position multiple times after the needle body is inserted into the lancing aid. Furthermore, it is the examiner's position that the needle is also configured to move between the second resting position and the lancing position after the blocking mechanism is actuated.

7. **Claims 12, 14, 21, and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Le Vaughn (US 2005/0015020 A1) in view of Looper (US 2003/0114839 A1).

LeVaughn discloses a lancing device (see entire document) comprising a housing, lancing aid, and a plurality of lancets within a magazine cartridge ([0009]). Each lancet comprises a needle tip and body so that the magazine cartridge overlaps the instantly claimed lancet system ([0107]). The magazine is removable from the lancing aid device ([0014], [0098]). A spring element interacts with the lancet body connected to the lancet system and clearly overlaps the instantly claimed holding element (Figure 4).

The lancets tips are secured with a protective cap (147) for sterility ([0107]). The caps are removed prior to puncturing the patient ([0020]). Therefore, the protective caps clearly overlap the instantly claimed protective portion. An opening is provided in the housing for the needle tip to pass through when puncturing the patient ([0108]). A drive mechanism (44) is also provided for to activate the lancet needles ([0106], [0109]).

LeVaughn does not specifically disclose a blocking mechanism that prevents the lancet system from re-use after being removed from the lancing aid. However, LeVaughn is open to various modifications and changes ([0134]).

Looper discloses a surgical device wherein a distal end effector is prevented from re-use (see entire document). The end effector includes a biopsy collector, which encompasses lancet devices, and is connected to the shaft of the surgical device through a frangible portion ([0014]; [0017]; [0040]). Once the distal biopsy collector has

been utilized and is contaminated, the frangible connection is distorted so that the connection between the surgical device and the biopsy collector is prevented (Figures 2 and 3). This assures that the biopsy collector is used only once for safety ([0043]; [0047]). Therefore, Looper teaches a blocking method that advantageously prevents re-use of a biopsy/lancet device.

It is well known in the art to one of ordinary skill that contamination from a lancet can poses a health hazard if not properly handled. Once a lancet has been inserted into a patient it is contaminated and should not be re-used. Looper teaches an advantageous blocking method wherein the biopsy collector is prevented from being used more than once so that a contaminated biopsy collector is not re-used. Since LeVaughn is open to various modifications and Looper teaches an advantageous way to prevent a lancet system from being used more than once, it would have been obvious to one of ordinary skill at the time of the invention for the lancet device of LeVaughn to comprise the blocking mechanism of Looper so that the lancet system of LeVaughn has a frangible connection with the lancing aid.

Allowable Subject Matter

8. **Claims 19, 27-28, and 33** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments, filed 7/31/2007, have been fully considered and are persuasive. All previous rejections and objections have been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Todd E. Manahan
SPE 3731

10/12/2007
ATL